

REMARKS

In the Office Action, claims 11-14, 16-18 and 26 are rejected under 35 U.S.C. § 112, second paragraph; claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 102; and claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 103. Claims 11, 19, 23 and 26 have been amended. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made.**" Applicants respectfully submit that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, claims 11-14, 16-18 and 26 are rejected under 35 U.S.C. § 112, second paragraph. The Patent Office asserts that claim 11 is indefinite with regard to the differences between the claim terms "treatment" and "prophylaxis". The Patent Office further asserts that claim 26 is indefinite with respect to the recitation of the claim term "cfu/ml".

With respect to the rejection of claim 11, Applicants believe that this rejection is improper. Claim 11 recites a method for the treatment or prophylaxis of calcium deficiencies in a mammal. The methods for the treatment of calcium deficiencies include administering the nutritional composition to the mammal that is already experiencing calcium deficiencies. The methods for the prophylaxis of calcium deficiencies includes administering the nutritional composition to the mammal at risk of calcium deficiencies for prevention. In view of same, Applicants believe that one skilled in the art would clearly recognize the differences between the use of the claim terms "treatment" and "prophylaxis" as required by claim 11. Therefore, Applicants respectfully submit that claim 11 fully complies with 35 U.S.C. § 112.

With respect to claim 26, this claim has been amended in a similar way as claim 14 was previously amended. In this regard, Applicants have amended claim 26 so that it is clear that a

liquid composition is referred to in claim 26. Therefore, Applicants respectfully submit that amended claim 26 fully complies with 35 U.S.C. § 112.

Accordingly, Applicants respectfully request that the rejection of claims 11-14, 16-18 and 26 under 35 U.S.C. § 112, second paragraph be withdrawn.

In the Office Action, claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 102. More specifically, claims 11-13, 16-19 and 21-25 are rejected in view of U.S. Patent No. 5,578,302 ("302 Patent"); and claims 11-14, 16-19 and 21-26 are rejected in view of U.S. Patent No. 5,494,664 ("664 Patent"). The Patent Office essentially asserts that either of these references discloses each and every feature of the claimed invention.

Applicants respectfully submit that the anticipation rejections are improper. Of the pending claims, claims 11, 19 and 23 are the sole independent claims. Claim 1 recites a method for the treatment or prophylaxis of calcium deficiencies in a mammal having or at risk of calcium deficiency; claim 19 recites a method for increasing absorption of calcium from a diet; and claim 23 recites a method for improving the absorption of calcium in a mammal. Each of independent claims 11, 19 and 23 includes, in part, the step of administering to the mammal a nutritional composition that includes one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal.

In contrast, nowhere does the '302 Patent or the '664 Patent disclose or suggest a number of features of the claimed invention. Indeed, the Patent Office even admits that the '302 Patent or the '664 Patent are silent with respect to particular effects as claimed such as treatment or prophylaxis of mineral deficiencies including calcium in a mammal or for improving absorption of minerals including calcium from the diet. As such, the Patent Office has relied upon three

references in addition to the '302 Patent or the '664 Patent in support of the rejection of the claims under 35 U.S.C. § 103.

Of course, the Court of Appeals for the Federal Circuit has held that "when more than one reference is required to establish unpatentability of the claimed invention, anticipation under § 102 cannot be found, and validity is determined in terms of § 103." *Continental Can Co. USA v. Monsanto Co.*, 20 U.S.P.Q.2d 1746, 1748 (Fed. Cir. 1991). Thus, it is clearly improper for the Patent Office to reject the claimed invention under 35 U.S.C. § 102 where, on the other hand, the Patent Office cites to multiple references in addition to the '302 Patent or the '664 Patent to support the obviousness rejection regarding the claimed invention.

In any event, the '302 Patent or the '664 Patent are clearly deficient with respect to a number of features of the claimed invention. For example, each of the '302 Patent and the '664 Patent merely relates to general health benefits. Neither of these references discloses mineral absorption in general, let alone calcium absorption in particular. In contrast, claim 1 recites a method for the treatment or prophylaxis of calcium deficiencies in a mammal; claim 19 recites a method for increasing absorption of calcium from a diet; and claim 23 recites a method for improving the absorption of calcium in a mammal. Indeed, the Patent Office appears to give little, if any, patentable weight to these features as required by the claimed invention. This is clearly improper.

Further, each of the independent claims are limited to administering the nutritional composition to a mammal that requires increased calcium absorption. Indeed, there are a number of reasons why a mammal would require increased mineral absorption, such as for pregnancy, or old age as disclosed in the Specification. In contrast, the '664 Patent is particularly directed to mammals that require an anti-diarrhoeic (see, '664 Patent, column 1, lines 35-46) and the '302

Patent is merely directed to patients that require an anti-ulcer agent (see, '302 Patent, column 1, lines 35-44).

Moreover, nowhere do either of the '302 Patent or the '664 Patent disclose or suggest the methods of the claimed invention that require administering the nutritional composition that includes one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal. Support for this amendment can be found, for example, in the Specification on page 5, lines 13-15.

Applicants have demonstrated that the *Lactobacillus* bacteria administered in a living state can facilitate the absorption of minerals in the mammal. In Example 1 of the Specification, for example, a human colon cell line is exposed to living *Lactobacilli* in an in vitro model. Nowhere do either of the '302 Patent or the '664 Patent disclose or suggest that the direct interaction between intestinal cells and living *Lactobacilli* can facilitate or improve the absorption of minerals by the intestinal cells as required by the claimed invention. Therefore, Applicants believe that the '302 Patent or the '664 Patent clearly fail to disclose or suggest a number of features of the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejections with respect to the claimed invention be withdrawn.

In the Office Action, claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 103 as being unpatentable over the '302 Patent or the '664 Patent and further in view of *Yaeshima*, *Yoshida* and *Sellars*. The Patent Office primarily relies on the '302 Patent or the '664 Patent and thus relies on the combined teachings of the remaining cited references to remedy the deficiencies of the '302 Patent or the '664 Patent. Applicants respectfully submit that this rejection is improper for the reasons set forth below.

At the outset, the primary references, namely, the '302 Patent or the '664 Patent, are clearly deficient with respect to a number of features of the claimed invention for substantially the same reasons as discussed above. Indeed, the '302 Patent or the '664 Patent are silent with respect to particular effects as claimed such as treatment or prophylaxis of mineral deficiencies including calcium in a mammal or for improving absorption of minerals including calcium from the diet as even admitted by the Patent Office.

Further, Applicants do not believe that the Patent Office can rely solely on the combined teachings of the remaining references to remedy the deficiencies of either the '302 Patent or the '664 Patent. As previously discussed, the independent claims have been amended to require that the *Lactobacillus* bacteria is administered in a living state to the intestines of the mammal. Applicants have surprisingly shown that living *Lactobacilli*, in direct interaction with intestinal cells, are able to facilitate or improve the absorption of minerals by intestinal cells. See, Specification, page 9, line 35 to page 10, line 2. This is clearly not linked to the ability of acidifying the experimental medium as indicated in the Specification on page 9, at lines 26-29. In this regard, the methods of the claimed invention are not directed to the effects of a fermented medium, or, the product that is produced by the bacteria, but to the direct interaction between living *Lactobacilli* and intestinal cells that can facilitate or improve the absorption of minerals (i.e., calcium) by the intestinal cells.

In contrast, Applicants believe that, at most, the cited art merely suggests metabolites produced by lactobacilli and which are present in fermented dairy products may have a desirable effect on mineral absorption. This is a clear teaching away from the present invention where it is found that the immediate action of the living *Lactobacillus* bacteria in the intestines leads to an increase of mineral absorption.

Indeed, *Sellars*, for example, discloses that the presence of minute quantities of lactic acid can influence the rate of absorbed minerals. One of the reasons for increased growth in animals fed fermented products was increased bio-availability. Further, *Sellars* discloses that, for example, lactose, lactic acid and vitamin D all increased absorption of minerals. See, *Sellars*, page 102. Lactic acid is a metabolite of fermenting *Lactobacillus*. In view of same, Applicants believe that one skilled in the art would clearly conclude the cited art fails to disclose or suggest to the extent that it effectively teaches away from direct interaction of living *Lactobacillus* bacteria in the intestines thereby increasing the absorption of calcium as required by the claimed invention.

Further, in *Yoshida*, this reference merely compares germ-free, namely, gnotobiotic mice (e.g., devoid of bacteria, even in the intestines) to mice that were fed with bacteria from the human intestines. The result of the *Yoshida* study indicated that gnotobiotic mice did not suffer deleterious effects with respect to mineral absorption. This clearly suggest that the presence or absence of bacteria has no effect on mineral absorption. Therefore, Applicants believe that one skilled in the art, viewing same, would conclude that *Yoshida* clearly teaches away from the direct interaction between living *Lactobacillus* bacteria in the intestines thereby increasing the absorption of calcium as required by the claimed invention.

Nor does *Yaeshima*, when added to the combination of references, disclose or suggest the claimed invention. First, it must be pointed out that *Yaeshima* does not mention lactobacillus but a bacteria species of a non-related gender. In this regard, *Yaeshima* discloses *Bifidobacterium longum* together with lactulose. Further, no gender, but a species-specific effect is described (*B. longum*) only. Perhaps, most importantly, it was found that *B. longum* alone did not lead to a significant increase in calcium absorption but, that lactulose must be present (see Figure 13). In

this regard, *Yaeshima*, at most, found a lactose-dependent effect on calcium absorption. Again, this clearly teaches away from direct interaction between living *Lactobacillus* bacteria in the intestines thereby increasing the absorption of calcium as required by the claimed invention.

In view of same, nowhere does the cited art, even if combinable in any hypothetical combination, disclose or suggest a number of features of the claimed invention, such as living *Lactobacillus* bacteria within the intestines and in the vicinity of the intestinal cells can increase the absorption of calcium by the cells. This effect is surprising and contrary to the teaching of the cited art, e.g., *Sellars*, which suggests that the effect is dependent on an acidified medium (dairy product). In contrast, the Applicants have demonstrated that even without a fermented (acidified) dairy product lactobacilli directly and solely causes the intestinal cells to absorb calcium at a higher rate. Thus, one skilled in the art, viewing the combined teaching of the secondary references, would not be inclined to modify the primary references alone or in combination to arrive at the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend Claims 11, 19, 23 and 26 as follows:

11. (Three Times Amended) A method for the treatment or prophylaxis of calcium deficiencies in a mammal having or at risk of calcium deficiency comprising the steps of enterally administering to the mammal a nutritional composition comprising one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal.

19. (Three Times Amended) A method for increasing absorption of calcium from a diet comprising the steps of enterally administering to a mammal requiring increased calcium absorption a nutritional composition comprising one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal.

23. (Three Times Amended) A method for improving the absorption of calcium in a mammal comprising the steps of enterally administering to the mammal requiring increased calcium absorption a nutritional composition comprising one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal.

26. (Amended) The method of Claim 23 wherein the nutritional composition is a liquid and comprises about 10^7 to about 10^{11} cfu/ml of the *Lactobacillus* bacteria.